



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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December 15, 2003

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-12  
Stephen B. Giles, President  
Jumbo Foods, Inc.  
11502 Cyrus Way  
Mukilteo, Washington 98275

WARNING LETTER

Dear Mr. Giles:

On September 24, 26, and 29, 2003, we inspected your seafood processing facility located at 11502 Cyrus Way, Mukilteo, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a) (4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C 342 (a)(4). Accordingly, your tuna salad sandwiches in modified atmospheric packaging (MAP) are adulterated in that this product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations and the Fish and Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001 (the Hazard Guide), through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for tuna salad sandwiches in modified atmosphere packaging (MAP) does not list the food safety hazard of *Clostridium botulinum*.

Your process of placing your sandwiches in wedge shaped containers, not sealing them, and flushing out the residual oxygen from the containers with a combination of nitrogen and carbon dioxide creates a modified atmosphere and constitutes reduced oxygen packaging. During the inspection, Mr. Johnson verified to our investigator that the finished sandwiches have no more than █% oxygen present inside the package and that you perform quality control checks to ensure that no more than █% oxygen is present in

any pack. Moreover, since you contend that this packaging achieves a 24-day refrigerated shelf life, this provides time for growth and toxin production of *Clostridium botulinum* if the product is subjected to mild temperature abuse..

Because you are using modified atmospheric (i.e., reduced oxygen) packaging, *Clostridium botulinum* is a hazard that is reasonably likely to occur in your product. We acknowledge receipt of your letter dated November 20, 2002, in which you take the position that *Clostridium botulinum* is not a reasonably likely hazard in your final product. We disagree. The ingredients in the tuna salad mix other than the canned tuna (i.e., celery and onions), are of concern because they can be a potential source of non-proteolytic *Clostridium botulinum* types B, E, and F. These strains of *Clostridium botulinum* are not restricted to seafood products. The *Clostridium botulinum* spores can be found in soil and can enter your sandwiches via raw vegetable materials. Once introduced into the final product, the anaerobic conditions present in reduced oxygen and/or modified atmospheric packages such as yours are conducive to the growth of the *Clostridium botulinum* spores with the potential for toxin formation. Consequently, there must be controls in place to prevent growth and toxin formation from *Clostridium botulinum* in your modified atmospheric packaged tuna salad sandwiches. FDA recommends as control strategies that:

- If you use refrigeration as the sole barrier to outgrowth of nonproteolytic *Clostridium botulinum* (i.e., where the spores have not been destroyed in-package and where there is no secondary barrier), you ensure that the temperature is maintained at 38° F or below from packing to consumption. Once your tuna salad sandwiches are placed into the modified atmosphere packaging, *Clostridium botulinum* becomes a hazard that is reasonably likely to occur due to the reduced oxygen available inside the container. Maintenance of the temperature at 38° F or below is necessary for the safety of your product even after the product is no longer in your control. FDA recommends the use of time temperature integrators (TTIs) on each individual consumer package to ensure temperature control throughout distribution.

or

- You apply a secondary barrier to *Clostridium botulinum* in the form of controlling the level of acidity by reducing pH to 5.0 or below; by controlling water activity to below 0.97; by increasing water phase salt to at least 5% or greater; or a combination of these factors in conjunction with maintaining the temperature at 40°F or below.


We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. You may wish to include in your response documentation such as your revised HACCP plan, and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation (21 CFR 123), and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Elrand at 425-483-4913.

Sincerely,



Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: WSDA with disclosure statement